Ministry of Economic Development
Manatū Ōhanga
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PCT/NZ2004/000130

CERTIFICATE

This certificate is issued in support of an application for Patent registration in a country outside New Zealand pursuant to the Patents Act 1953 and the Regulations thereunder.

I hereby certify that annexed is a true copy of the Provisional Specification as filed on 30 June 2003 with an application for Letters Patent number 526775 made by David Peter Shaw.

Dated 8 July 2004.

Neville Harris
Commissioner of Patents, Trade Marks and Designs

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Patents Form No. 4

Patents Act 1953

PROVISIONAL SPECIFICATION

CUFFS FOR MEDICAL APPLICATIONS

I, David Peter SHAW, of Cossars Road, Tai Tapu, R.D. 2, Christchurch, New Zealand, a New Zealand citizen, do hereby declare this invention to be described in the following statement:

Title: Cuffs for Medical Applications

Technical Field

The present invention relates to cuffs for medical applications, i.e. to cuffs which surround components which have to be positioned in the body. Some cuffs are sewn in place, others are simply positioned around other components.

Background Art

At present, cuffs usually are made of fabric, generally a very tightly woven Dacron (trademark) material which is both dense and flexible. Also, Dacron can be readily penetrated by a sewing needle if the cuffs are sewn in.

However, fabric cuffs present a huge surface area and hence a large number of sites in which bacteria can hide from the body's defences; this greatly increases the risk of infection, and makes any infection which does occur, very difficult to treat. A further drawback of fabric cuffs is that the body regards the fabric as a "foreign body", so that if the cuff is infected, it is almost impossible to sterilise with antibiotics or for the body's defences to phagocytose on the surface of the fibre.

Thus, if a fabric cuff becomes infected it generally is necessary to replace the cuff, and often to replace both the cuff and the component being held in place by the cuff. This involves an additional surgical procedure on the patient who may already be seriously ill, which obviously is undesirable.

Disclosure of Invention

It is an object of the present invention to provide a cuff for medical use which overcomes the above described drawbacks.

The present invention provides a cuff for medical use in which the cuff is made of a flexible openwork structure of a medically acceptable metal wire.

As used herein, the term "medically acceptable" means a metal which is non-toxic to the body and preferably which is inert in the body, i.e. does not provoke a "foreign body" reaction when implanted in the body. It is envisaged that the cuff of the present invention suitably would be made from titanium wire or medically approved titanium alloy wire (for example the nickel/titanium Nitenol (trademark) alloys), but other medically acceptable metals could be used providing they can be drawn as fine flexible wires.

It is envisaged that a flexible openwork structure can be made from the wire, e.g. by using a knitting type of process or by a weaving process, or by manufacturing chain mail, (i.e. a series of separate interlocked rings of wire), or by using a 'steel wool' type of structure. The finished openwork structure must be able to flex without permanently bending and (in the case of a sewn cuff) must provide a large number of apertures through which a sewing needle can be inserted.

Brief Description of Drawings

By way of example only, preferred embodiments of the present invention are described in detail with reference to the accompanying drawings in which:-

Figures 1 and 2 respectively show perspective views of the upper and lower surfaces of a replacement heart valve fitted with a sewn-in cuff in accordance with the present invention; and

Figure 3 shows a sketch side view of a cuff in accordance with the present invention used in connection with a Hickman line.

Best Mode for Carrying out the Invention

Referring to Figures 1 and 2, a widely used design of replacement heart valve 2 consists of a titanium rim 3 which provides support for the valve flap 4. The heart valve itself is a 'Medtronic Hall' mechanical valve of known design and will not be described in detail.

The rim 3 supports a cuff 5 made of knitted titanium wire. The cuff 5 is the same basic shape as the Dacron cuff it replaces:- an inner annulus 6 which fits tightly around the rim 3, holding the cuff 5 onto the valve 2, and an outer annulus 7, which is formed integrally with the inner annulus 6 but which is of larger diameter.

The cuff 5, because of its knitted construction, is flexible and provides a very large number of apertures through which a sewing needle can be inserted, to sew the cuff into the body. The cuff thus provides a secure but flexible seating for the valve. The cuff can be sewn into place as easily as the Dacron cuff it replaces, but is very much less prone to bacterial infection and, if it becomes infected, can be sterilised effectively with antibiotics, without resorting to surgery.

A further advantage is that titanium and titanium alloys not only are regarded as inert by the body, but promote good tissue growth. Thus, as the body heals around the inserted valve, tissue will readily grow over the cuff, reducing the incidence of paravalvular leaks. In addition, it is envisaged that the cuff of the present invention will provide superior endothelisation, reducing thrombenbolic rates and giving reduced pannus formation.

Referring to Figure 3, a cuff 10 in accordance with the present invention is shown in

use in combination with a Hickman line 11. The line 11 is inserted through the skin 12 in known manner and the cuff 10 is located just below the skin, and encircles the outer surface of the Hickman line, to prevent infection entering the body through the aperture which admits the line 11, and travelling down the outer surface of the line.

The cuff 10 consists of a cylinder formed from knitted titanium wire. The inner diameter of the cylinder is such that the cylinder can be press fitted over the Hickman line 11. The cuff 10 is secured in place by frictional contact with the exterior of the Hickman line.

It will be appreciated a cuff formed in accordance with the present invention may be used in any of a wide range of applications where at present fabric cuffs are used, and is not limited to the particular applications described in detail above. For example, cuffs in accordance with the present invention may be used as barrier cuffs in combination with peritoneal dialysis catheters, held in position by frictional contact. Further, the cuffs of the present invention may be used to form annuloplasty bands or rings (a band being an incomplete ring) which are sewn in place and used to tighten an annulus or support an annulus after valve repair.

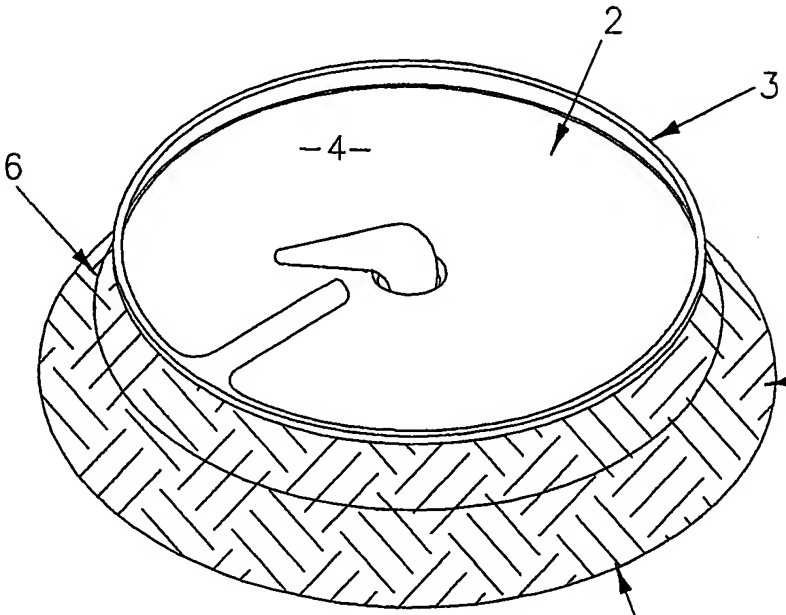

Fig.1

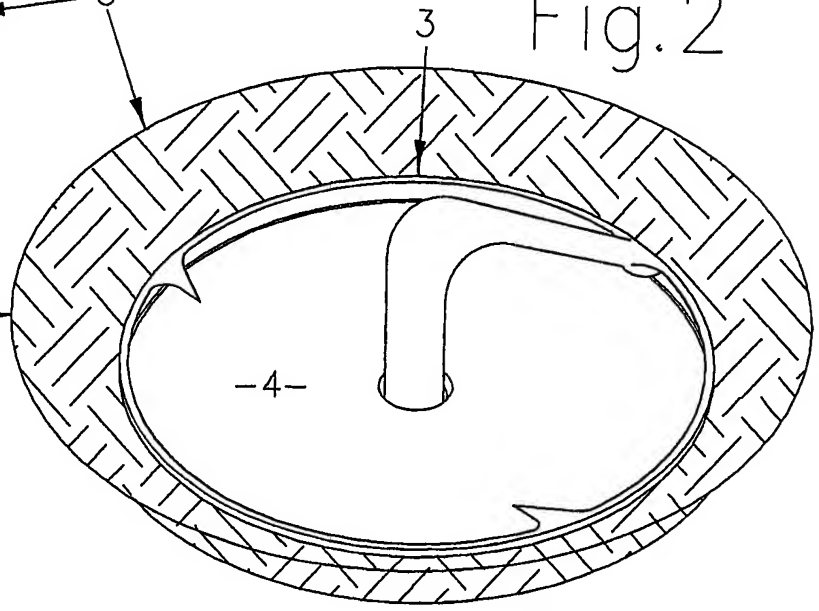

Fig.2

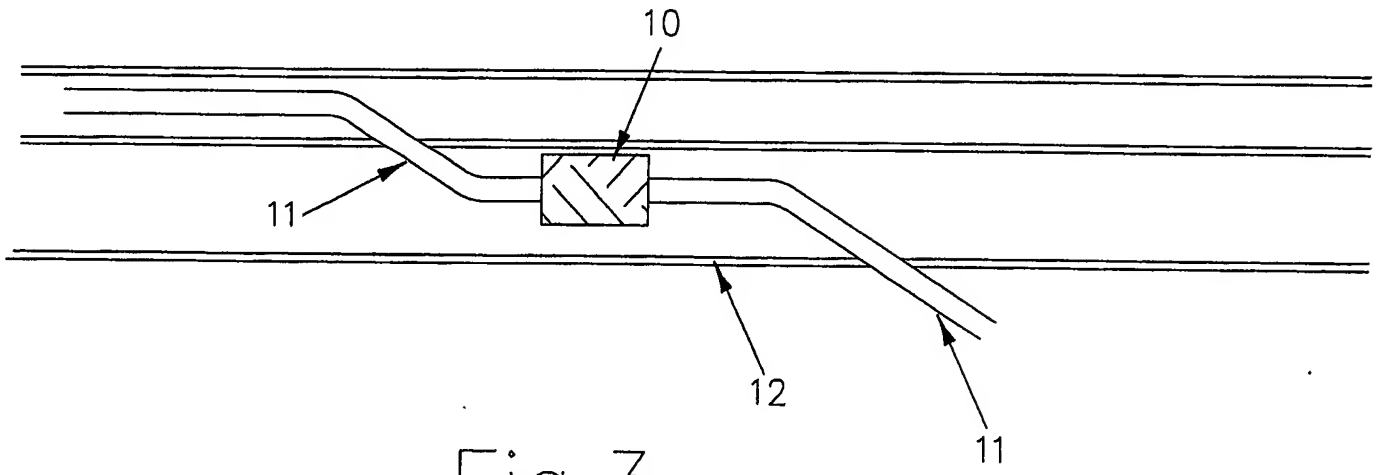

Fig.3